REMARKS

I. STATUS OF THE APPLICATION

Claims 1-13 were pending in the Application. In the Office Action, the Examiner:

(a) accepted Applicant's terminal disclaimer to overcome the rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,607,745;

(b) accepted Applicant's argument and withdrew the rejection of claims 1-13 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention;

(c) accepted Applicant's argument and withdrew the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;

(d) maintained the rejection of claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

In this response, Applicant respectfully submits the following comments and amendments to claims 11-13. Claims 1-10 remain in the Application but are not amended. Applicant respectfully submits that the following remarks herein traverse or overcome the Examiner's rejections to the Application.

II. NO NEW MATTER IS INTRODUCED BY WAY OF AMENDMENT

Applicant respectfully submits that no new matter has been added by amending claims 11-13. Specifically, the amendments to claim 12 were to place claim 12 in independent form by incorporating the content of independent claim 11. Accordingly, claim 11 has been cancelled. Claim 13 was also amended to depend from amended claim 12. Applicant respectfully submits

that the amendments are supported by the originally filed Application and do not add new matter. Accordingly, Applicant requests that the amendments be entered and that the Application proceed to allowance for the reasons provided herein.

III. THE REJECTION OF CLAIMS 1-13 UNDER 35 U.S.C. § 102(e) AS ALLEGEDLY BEING ANTICIPATED BY PIERCE IS OVERCOME AND SHOULD BE WITHDRAWN

In the Office Action, the Examiner maintained the rejection of claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by Pierce. Applicant respectfully submits that the rejection of claims 1-13 is overcome and should be withdrawn because (a) the Application is not claiming the same invention as Pierce, (b) the claims of the Application and Pierce are patentably distinct, (c) the limitations contained within MPEP §§ 715.05 and 2304.02(c) and 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) do not apply to the present Application, and (d) Pierce does not constitute prior art to the present Application.

In the Office Action, the Examiner stated that "[s]ince applicant is claiming the same invention as Pierce, the declaration of prior inventorship is not sufficient to overcome the 35 USC §102(e) rejection. See MPEP § 715.05." Office Action, page 3. In addition, the Examiner stated that "Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c). Office Action, page 3. Applicant respectfully submits that these statements are inapplicable to the Applicant's declaration of prior inventorship dated November 3, 2006 (the "Declaration"), and as such, the Declaration is indeed sufficient to overcome the present rejection of claims 1-13 under 35 U.S.C. § 102(e).

A. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION AND THEREFORE APPLICANT'S DECLARATION IS EFFECTIVE TO OVERCOME THE 35 U.S.C. § 102(E) REJECTION

Applicant respectfully submits that the limitations of MPEP § 715.05 do not apply to the present application. MPEP §715.05 presently states the following in the opening paragraph:

> When the reference in question is a noncommonly owned U.S. patent or patent application publication ***claiming the same invention*** as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 41.202 instead of 37 CFR 1.131.
> (emphasis added)

In addition, MPEP §715.05 states that "[a] 37 CFR 1.131 affidavit is ineffective to overcome a United States patent or patent application publication, not only where there is a verbatim correspondence between the claims of the application and of the patent, ***but also where there is no patentable distinction between the respective claims***." (citations omitted, emphasis added).

Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the Declaration, and the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce.

1. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION BECAUSE THE PRESENT CLAIMS DO NOT CLAIM THE SAME INVENTION AS PIERCE

Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, the limitations of MPEP 715.05 do not apply. Specifically, because the claims, as presently amended, do not claim the same invention as Pierce, the previously submitted Declaration is effective to overcome the maintained 35 U.S.C. § 102(e) rejection.

The claims of the Application, as presently amended, include claims for a method for relieving joint pain or other discomforts associated with joint disorders and claims for a nutritional supplement. Pierce includes nine (9) method claims (claims 20-28) and nineteen (19) composition claims (claims 1-19). Applicants respectfully submit that as will be demonstrated below, the claims of the present Application ***do not claim the same invention*** as claimed in Pierce.

THE METHOD CLAIMS

Applicant respectfully submits that the method claims of the present Application, as amended, ***do not claim the same invention*** as claimed in the method claims of Pierce.

Claims 20-28 of Pierce are the only method claims included within Pierce. Claim 20, the only independent method claim of Pierce, includes the following general elements:

a. "A method of treating osteoarthritis...[and other disorders]..., said method comprising..."
b. "...orally administering..."
c. "...to [a] mammal..."
d. "...a therapeutically effective amount..."
e. "...of the composition of claim 1."

Regarding method element (e) above, the composition of claim 1 of Pierce includes the following elements:

w. "An orally administrable Chondroprotective/Restorative composition..."
x. "...gel or paste form..."
y. "...an effective amount of hyaluronic acid or its pharmaceutically acceptable salts..."
z. "...a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Accordingly, Applicant respectfully submits that claim 20 of Pierce, considering that method element (e) above references the composition described in composition elements (w) through (z), effectively includes method elements (a) through (d) and composition elements (w) through (z).

The present Application contains nine (9) method claims as presently amended, namely claims 1-7 and 12-13. Claim 12, as amended, is objectively the method claim of the present Application with the broadest scope (the fewest elements). Applicant's claim 12 contains the following elements:

i. "A method for relieving joint pain or other discomforts associated with joint disorders..."
ii. "...in a warm blooded vertebrate..."
iii. "...comprising the step of delivering to said vertebrate by oral ingestion..."
iv. "...a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof..."
v. "...wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight."

Applicant respectfully submits that claim 20 of Pierce, effectively including composition elements (w) through (z) of claim 1 of Pierce, ***does not claim the same invention*** as claimed in

Applicant's claim 12. Applicant respectfully submits the following list of differences between the two claims:

1. Composition element (x) of Pierce requires the composition to be in "gel or paste form." This element does not appear in Applicant's claim 12, which does not require the nutritional supplement referenced therein to be in "gel or paste form."

2. Composition element (z) of Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses." This element does not appear in Applicant's claim 12, which does not require the nutritional supplement referenced therein to include any type of "gelling or pasting agent."

3. Method element (v) of Applicant's claim 12 requires that "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight." Claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts.

Furthermore, Applicant respectfully submits that Applicant's claim 1 differs from Applicant's claim 12 as Applicant's claim 1 includes the delivery of a nutritional supplement "and a food acceptable carrier." Applicant respectfully submits that claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not include the element or limitation of a composition "and a food acceptable carrier."

Applicant respectfully submits that as provided above, Applicant's method claims differ from the method claims of Pierce, and accordingly, Applicant's method claims do not claim the same invention as the method claims of Pierce.

THE COMPOSITION CLAIMS

Applicant respectfully submits that the composition claims of the present Application, as amended, ***do not claim the same invention*** as claimed in the composition claims of Pierce.

Claims 1-19 of Pierce are the only composition claims included within Pierce. Applicant respectfully submits that no composition claim of Pierce claims the same invention as claimed in any of Applicant's pending composition claims.

Applicant respectfully submits that none of the composition claims of Pierce (claims 1-19) need to be considered as relevant to the present inquiry ***as each claim requires effective amounts of additional ingredients not claimed in Applicant's composition claims***. Specifically, the following claims of Pierce require the inclusion of one or more additional supplements/ingredients not required in Applicant's composition claims:

Claim 1: requires, at a minimum, "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Claim 2: requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 3: requires, at a minimum, "an effective amount of Glucosamine sulfate"

Claim 4: depends upon claim 3, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 5: requires, at a minimum, "an effective amount of Chondroitin sulfate"

Claim 6: depends upon claim 5, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 7: requires, at a minimum, "an effective amount of Glucosamine sulfate" and an effective amount of Chondroitin sulfate"

Claim 8: depends upon claim 7, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 9: requires, at a minimum, "an effective amount of a therapeutic drug" aside from hyaluronic acid and "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste"

Claim 10: depends upon claim 9, and requires that the therapeutic drug be selected from a group consisting over 200 compounds provided therein

Claim 11: claims a composition "in paste form" and requires, at a minimum, "a sufficient amount of molasses to make a paste."

Claim 12: depends upon claim 11, and requires, at a minimum, glucosamine sulfate

Claim 13: depends upon claim 12, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 14: depends upon claim 11, and requires, at a minimum, chondroitin sulfate

Claim 15: requires, at a minimum, "a sufficient amount of carboxymethylcellulose or its sodium salt to make a gel"

Claim 16: depends upon claim 15, and further requires glucosamine sulfate

Claim 17: depends upon claim 15, and further requires chondroitin sulfate

Claim 18: depends upon claim 15, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 19: depends upon claim 18, and further requires chondroitin sulfate

Applicant's claims 8-10 are the only composition claims included within the present Application. Applicant's claim 8, the only independent composition claim pending in the Application, includes the following general elements:

A. "A nutritional supplement consisting essentially of..."
B. "..an effective amount of hyaluronic acid, or a salt or digest thereof..."
C. "...and a food acceptable carrier..."
D. "...the nutritional supplement provided in an orally ingestible dosage form."

Applicant's claim 9, depending upon claim 8, includes the following element:

E. "...wherein the effective amount of hyaluronic acid is 1 to 6 mg."

Applicant's claim 10, which also depends upon claim 8, includes the following element:

F. "...wherein the orally ingestible dosage form is a capsule or gel seal."

Applicant respectfully submits that composition claims 8-10 of the Application neither contain nor require the supplements/ingredients identified above with respect to composition claims 1-19 of Pierce. Furthermore, as shown immediately above and as similarly referenced with respect to Applicant's method claim 1, Applicant's composition claim 8 includes a nutritional supplement "and a food acceptable carrier." Applicant respectfully submits that composition claims 1-19 of Pierce do not include the element or limitation of a composition "and a food acceptable carrier" as claimed in Applicant's composition claim 8.

Accordingly, Applicant respectfully submits that as provided above, Applicant's composition claims differ from the composition claims of Pierce, and accordingly, Applicant's composition claims do not claim the same invention as the composition claims of Pierce.

2. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION BECAUSE THERE IS A PATENTABLE DISTINCTION BETWEEN THE CLAIMS OF THE APPLICATION AND THE CLAIMS OF PIERCE

Applicant respectfully submits that because the claims of the Application are patently distinct from the claims of Pierce, the limitations of MPEP 715.05 do not apply. Specifically,

because the claims of the Application, as presently amended, are patently distinct from the claims of Pierce, the previously submitted Declaration is effective to overcome the maintained 35 U.S.C. § 102(e).

Applicant respectfully submits that in a similar fashion as described above with respect to the method and composition claims of the present Application and Pierce not claiming the same invention, those claims are also patently distinct from one another.

For example, the only independent method claim of Pierce (claim 20) claims a method of treating osteoarthritis and other disorders using the composition of claim 1 of Pierce. This method claim is patently distinct from the broadest method claim of the present Application (claim 12, as amended) as (1) Pierce requires the composition to be in "gel or paste form" which is not required by Applicant's claim 12, (2) Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses" which is not required by Applicant's claim 12, and (3) Applicant's claim 12 requires "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight", while claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts. As is clearly shown by these exemplary comparisons, the method claims of the present Application are patentably distinct from the method claims of Pierce.

A similar conclusion can be made with respect to the composition claims. As referenced above, each of claims 1-19 of Pierce requires at least one additional supplement/ingredient than is claimed in Applicant's composition claims 8-10. By way of example, (1) claim 1 of Pierce requires "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", (2) claims 2, 4, 6, 8, 13, and 18 of Pierce require "vitamins and minerals", (3) claims 3, 7, 12, and 16 of Pierce require glucosamine sulfate, and (4) claims 5, 7, 14, 17 and 19 of Pierce require chondroitin sulfate, each of which is not claimed or required by Applicant's composition claims 8-10. As is also clearly shown by these exemplary comparisons, the composition claims of the present Application are patentably distinct from the composition claims of Pierce.

Applicant respectfully submits that in addition to the foregoing, p*rima facie* evidence of Applicant's conclusion can be found when reviewing the prosecution history of Pierce. During the prosecution of Pierce, Examiner Devesh Khare performed a PLUS search on October 22, 2004. The date of this search is indicated on the Search Notes document for the Pierce application, a copy of which is enclosed for reference.

The PLUS search performed by Examiner Khare identified fifty (50) patent references, some of which are duplicate results. A copy of the PLUS search results for the Pierce application is enclosed with this Response. One of the patents identified by the PLUS search was U.S. Patent No. 6,607,745 to Leneau et al. (the "'745 Patent") (indicated by the arrow written in by counsel for Applicant), which is significant as the '745 Patent is the parent patent to the present Application. The present Application is a continuation-in-part of the application resulting in the '745 Patent.

Applicant respectfully submits that although the '745 Patent was identified by Examiner Khare, the next formal action taken by Examiner Khare, aside from the submission of interview summary documents, was the submission of a Notice of Allowability and a Notice of Allowance and Fees Due for the Pierce patent application. The '745 Patent was never referenced by Examiner Khare in a Notice of References Cited accompanying any office action issued during the prosecution of Pierce, and accordingly, Applicant respectfully submits that the identification of the '745 Patent in the PLUS search and the lack of citation of that reference by Examiner Khare in any office action of Notice of References Cited is *prima facie* evidence that the '745 Patent was patently distinct from Pierce.

In an office action dated May 4, 2006, the Examiner of the present Application presented an rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,607,745. In that rejection, the Examiner noted that the conflicting claims were "not identical", but that they were "not patentably distinct from each other" for the reasons provided therein. In response, Applicant submitted a terminal disclaimer along with the response to the May 4, 2006, office action, to obviate the rejection of claims 1-13.

Applicant respectfully submits that as the claims of the present Application were deemed to be "not patentably distinct" from claims 1-7 of the '745 Patent, and because Applicant filed a terminal disclaimer that was accepted by the Examiner, the claims of the present Application should be viewed in a similar fashion as were the claims of the '745 Patent as reviewed by Examiner Khare during the prosecution of Pierce. Specifically, Applicant respectfully submits that if the claims of the '745 Patent were not deemed to be material to the prosecution of Pierce,

and because the Examiner of the present Application has stated that specific claims of the '745 Patent are "not patentably distinct" from the claims of the present Application, the claims of the present Application are patentably distinct from the claims of Pierce.

Accordingly, Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the previously submitted Declaration, and the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e) and allow claims 1-10 and 12-13 to proceed to allowance.

B. APPLICANT IS NOT CLAIMING THE SAME INVENTION AS PIERCE, AND AS SUCH, 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) AND MPEP § 2304.02(c) DO NOT APPLY TO THE PRESENT APPLICATION

Applicant respectfully submits that because the Application does not claim the same invention as Pierce, the limitations of 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c) do not apply to the present Application.

In the Office Action, the Examiner stated that "Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c)." Office Action, page 3. Applicant respectfully submits that 37 C.F.R. § 41.202 ("Suggesting an interference.") and MPEP § 2304.02(c) ("Explaining Priority – 2300 Interference Proceedings") do not Apply to the present Application because there is a patentable distinction between the claims of the Application and the claims of Pierce as described above.

MPEP §2304.02(c) begins with a recitation of sections (a)(4), (a)(6) and (d)(2) of 37 C.F.R. §41.202, which lists the requirements an applicant must meet when suggesting an interference with another application or patent. Applicant respectfully submits that these sections, and the remaining sections of 37 C.F.R. §41.202 not cited within MPEP §2304.02(c) do not apply as Applicant is ***not*** suggesting an interference. Applicant respectfully submits that such a suggestion is not being made because, as is shown in Section **III(A)** above, the pending Application is not claiming the same invention as Pierce and because the pending claims of the Application are patentably distinct from the claims of Pierce. Accordingly, Applicant respectfully requests that any requirement to provide such a suggestion within the Office Action be withdrawn.

C. PIERCE DOES NOT CONSTITUTE PRIOR ART TO THE PRESENT APPLICATION AS THE DISCLOSURE OF THE PROVISIONAL APPLICATION FOR WHICH PIERCE CLAIMS PRIORITY DID NOT SUFFICIENTLY ENABLE THE PIERCE NON-PROVISIONAL PATENT APPLICATION

Applicant respectfully submits that notwithstanding the foregoing, Pierce does not qualify as prior art to the present Application. Specifically, the provisional patent application for which Pierce claims priority did not sufficiently enable the disclosure of the non-provisional Pierce application, and as such, the effective date of Pierce for purposes of its potential applicability to the present analysis prohibits Pierce from constituting prior art to the present Application.

1. THE PROCEDURAL HISTORY OF THE PIERCE APPLICATIONS

On October 3, 2000, the attorney for inventor Scott Pierce, John F. Dolan, filed U.S. Provisional Application No. 60/237,838, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'838 Application"). On October 2, 2001, another attorney for Scott Pierce, Isaac A. Angres, filed U.S. Nonprovisional Patent Application No. 09/967,977, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'977 Application"), claiming priority back to U.S. Provisional Application No. 60/237,838. U.S. Nonprovisional Patent Application No. 09/967,977 eventually issued as U.S. Patent No. 6,924,273 on August 2, 2005.

2. THE PROCEDURAL HISTORY OF THE LENEAU APPLICATIONS

On May 18, 2001, the attorney for inventor Harry Leneau, Jill Powlick of Barnes & Thornburg, filed U.S. Nonprovisional Application No. 09/860,425, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'425 Application"). The '425 Application eventually issued as U.S. Patent No. 6,607,745 on August 19, 2003. Prior to the issuance of the '745 Patent, the same attorney for inventor Harry Leneau filed a continuation-in-part application, namely U.S. Nonprovisional Application No. 10/629,880, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'880 Application"). The '880 Application claimed priority back to the '425 Application.

3. THE "INVENTION" OF THE '838 APPLICATION IS CLEARLY A COMPOSITION CONTAINING GLUCOSAMINE SULFATE, CHONDROITIN SULFATE, AND HYALURONIC ACID, AND NOT HYALURONIC ACID ALONE

Applicant respectfully submits that the "invention" disclosed by the Pierce '838 Application is clearly a composition containing glucosamine sulfate, chondroitin sulfate, and hyaluronic acid, and not a composition containing hyaluronic acid alone. The '838 Application, filed on October 3, 2000, disclosed a composition called "Chondrogen EQ" which was allegedly "the most unique chondroprotective / restorative agent available." '838 Application, page 1. The '838 Application, as shown by numerous references therein, makes it clear what the "invention" was within the '838 Application:

- "***The present invention***, which goes by the name Chondrogen EQ, was initially formulated ..." (emphasis added). '838 Application, page 1.

- "This highly palatable formulation is the first ***to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** in an easy to absorb, low molecular weight formula." (emphasis added) '838 Application, page 1.

- "***The present invention, with it's unique combination of GS, CS, and HA*** ..." (emphasis added). '838 Application, page 1.

- "As previously explained, ***the present invention comprises a highly palatable formulation, which is the first to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** ..." (emphasis added). '838 Application, page 3.

- "There is a beneficial effect when ***Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid*** are administered orally. Generally, the oral administration of embodiments ***of the present composition has a quicker clinical response than is produced when each component of the composition is given individually. A significant difference*** is an acute or a rapid relied in joint pain inflammation and swelling achieved by oral administration of the composition." (emphasis added) '838 Application, pages 4-5.

- "Another benefit is that ***embodiments of the present invention, with it's high dose of Glucosamine sulfate, Hyaluronic acid, and Chondroitin sulfate***, appears to have a synergistic effect which hastens the clinical response." (emphasis added) '838 Application, page 5.

- "***One embodiment of the present invention is a unique formulation that combines Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid into a paste formulation*** ..." (emphasis added). '838 Application, page 5.

- "Early clinical trials have shown that ***when the three products are combined***, they have a synergistic effect." (emphasis added) '838 Application, pages 5-6.

- "***Embodiments of the present invention possess the following advantages***: ... 2) ***Only combination of GS, CS, HA in a paste formulation*** ..." (emphasis added). '838 Application, page 6.

- "Because of their chemical similarities and the clinical reports of improvement of synovitis, ***HA has a synergistic effect with GS and CS when given orally.***" ..." (emphasis added). '838 Application, page 9.

As is shown by these statements within the '838 Application, it is clear that the "invention" of the '838 Application is a combination of Glucosamine sulfate (GS), Chondroitin sulfate (CS) and Hyaluronic Acid (HA). Additional support for this conclusion can be found in the only two exemplary formulations provided in the '838 Application:

- Page 7: Embodiment comprising 46.03% Glucosamine sulfate, 4.60% Chondroitin sulfate, and 0.18% Sodium hyaluronate. In this embodiment, of the 50.81% (46.03% + 4.60% + 0.18%) combined active ingredients, only 0.35% (0.18%/50.81%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

- Page 11 (unnumbered – page appearing after numbered page 10): Chondrogen EQ formulation comprising 36% Glucosamine sulfate, 4% Chondroitin sulfate, and 0.144% Sodium hyaluronate. In this embodiment, of the 40.144% (36% + 4% + 0.144%) combined active ingredients, only 0.36% (0.144%/40.144%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

As is clearly shown, these two formulations only contain a very minor fraction (0.18% and 0.144%, respectively), of sodium hyaluronate as compared to the remaining ingredients.

When viewing the three named active ingredients of the "invention" of the '838 Application (namely glucosamine sulfate, chondroitin sulfate and Hyaluronic Acid), sodium hyaluronate only comprises 0.35% and 0.36%, respectively, of those two formulations. In the first formulation, for example, the weight ratio to the largest active ingredient (glucosamine sulfate) to sodium hyaluronate is over 255 to 1. In the second formulation, the weight ratio of glucosamine sulfate to sodium hyaluronate is also very high (250 to 1).

4. THE '838 APPLICATION INTRODUCED, BUT DID NOT ENABLE, AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT ALSO CONTAINING GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE

Applicant respectfully submits that the '838 Application introduced, but did not enable, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate. Applicant acknowledges that the '838 Application does discuss the concept of oral administration of hyaluronic acid ("HA"), but Applicant respectfully submits that the introduction of this concept within the '838 Application included no evidence whatsoever to support the conclusions made therein. For example, page 5 of the '838 Application states the following:

> Another benefit received is that of oral preparation and administration of HA given, for example, in the equine in any formulation. The administration of the HA composition orally and having a clinical effect eliminates more evasive procedures.

In addition, page 9 of the '838 Application states the following:

> Clinically, responses are seen in 7 to 10 days vs three to four weeks or not at all when GS and CS are given without HA. Therefore, we have seen a dramatic decrease in synovitis when HA is combined with GS and CS. ***This leads us to***

> ***conclude that HA is absorbed orally and effective*** either ***alone*** or in combination with GS and CS. Therefore, an additional embodiment of the invention comprises a composition including HA and any acceptable carrier, such as the paste formulation disclosed herein and any other liquid, powder, gel or similar type carrier. (emphasis added).

Applicant respectfully submits that although the '838 Application states that "an additional embodiment of the invention comprises a composition including HA and any acceptable carrier", this statement contains no support from any other portion of the '838 Application and actually contradicts other statements in the application. This particular statement follows the prior two sentences in the '838 Application which state (in summary) that that clinical responses are seen when GS and CS are provided ***without HA***, and that a dramatic decrease in synovitis is seen ***when HA is combined with GS and CS***. As the '838 Application clearly discloses and intends to focus on an orally administrable composition containing GS, CS, and HA, a conclusion that the oral administration of HA alone without any evidence in support and that contradicts other statements within the same application, is clearly not enabled.

5. THE ONLY SUPPORT WITHIN THE PIERCE APPLICATIONS FOR AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE APPEARED WITHIN THE '977 APPLICATION AND NOT THE '838 APPLICATION

Applicant respectfully submits that the only support within the Pierce applications for an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate appeared within the '977 Application and not the '838 Application. As discussed in Section III(C)(4) above, the '838 Application introduced, but

provided no support for, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate.

Applicant respectfully submits that support for such a product was first introduced in the on page 10 of the '977 Application. Starting on page 10, the '838 Application discusses the treatment of ten horses with an oral gel and provides data regarding the same on Tables 1 and 2 appearing on pages 12-13. By way of example, the "TREATED HORSES" section of Table 2 shows that horses 101, 105, 106, and 109 "Improved" during treatment using the hyaluronic acid gel.

Applicant respectfully submits that this data, first appearing in the '977 Application, is the first time the concept of an "effective" orally administrable composition containing hyaluronic acid and not containing glucosamine sulfate and chondroitin sulfate was enabled in either of the Pierce applications.

6. BECAUSE THE '838 APPLICATION DID NOT ENABLE AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE, PIERCE IS NOT PRIOR ART WITH RESPECT TO THE PRESENT APPLICATION

Applicant respectfully submits that because the '838 Application did not enable an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate, Pierce is not prior art with respect to the present Application.

Applicant respectfully submits that the parent application to the present Application, namely the '425 Application, was filed on May 18, 2001. Pierce's provisional application (the

'838 Application) was filed on October 3, 2000, approximately 7 ½ months prior to the filing of the '425 Application. Pierce then converted the '838 Application to the '977 Application on October 2, 2001, approximately 4 ½ months after Leneau filed the parent application (the '425 Application) to the present Application (the '880 Application).

Applicant respectfully submits that as pertaining to any orally administrable composition which may be disclosed within either of the Pierce applications that contains hyaluronic acid but not glucosamine sulfate or chondroitin sulfate, the '977 Application, and not the '838 Application, provides data enabling such a composition. Accordingly, and because the '977 Application was filed ***after*** the parent application (the '425 Application) for which the present Application (the '425 Application) claims priority, Pierce cannot be considered prior art with respect to such a composition. Accordingly, Applicant respectfully submits that the Pierce patent is not prior art to the present Application, and as such, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e) and allow claims 1-10 and 12-13 to proceed to allowance.

IV. ADVISORY ACTION REQUESTED

Applicant respectfully submits that this Response is being effectively filed within two months of the mailing of the final Office Action. Accordingly, Applicant respectfully requests an Advisory Action from the Examiner stating that the present Application is in a condition for allowance. Should the Examiner recognize any matters of form that the Examiner can change without authorization from Applicant (under MPEP § 1302.04), Applicant respectfully requests

that such changes be made prior to the issuance of the Advisory Action acknowledging that the Application is in a condition for allowance.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicant has made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of this Application is respectfully requested. In the event the Applicant has inadvertently overlooked the need for a payment of a fee or extension of time, the Applicant conditionally petitions therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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MCR
Enclosures: Search Notes for U.S. Application No. 09/967,977
PLUS Results for U.S. Application No. 09/967,977
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PLUS Search Results for S/N 09967977, Searched October 22, 2004

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present. PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

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Search Notes

Application No.	Applicant(s)	
09/967,977	PIERCE, SCOTT W.	
Examiner	**Art Unit**	
Devesh Khare	1623	

SEARCHED			
Class	Subclass	Date	Examiner
514	54, 62, 2, 56		
424	423, 434.1,		
	450, 484,		
	756, 499,		
	548, 639,		
	486, 488.		
536	21, 54 18.7,		
	55.1, 55.2	10/22/04	DK

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
514	54, 62 2, 56		
424	423, 434, 450,		
	548 639,		
536	21, 54, 18.7, 55.1.	10/22/04	DK

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
EAST Search	9/5/03	DK
	10/22/04	DK
PLUS Search	10/22/04	DK.